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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,376	03/16/2000	Ralf M. Luche	200125.407	2363

500 7590 07/17/2003

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
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SEATTLE, WA 98104-7092

EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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DATE MAILED: 06/30/2003

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Office Action Summary	Application N .	Applicant(s)	
	09/527,376	LUCHE ET AL.	
	Examin r	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8-14* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed May 27, 2003 (Paper No. 13) canceling claims 15-50 has been entered.

Claims 1-14 are pending.

Election/Restrictions

Applicant's election of Group II, claims 1-14, in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The examiner notes that the Restriction requirement contained an inadvertent typographical error by which claim 1 was included in both Group I and Group II. Group II as it is obvious from the description thereof consists of claims 2-14.

Claim 1 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Election was made without traverse in Paper No. 13.

Claims 2-14 are under consideration in the current Office action.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. 37 CFR 1.821(d) requires the use of assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of incompliance where the sequence containing more than ten nucleotides or four amino acids is given without a sequence identifier: Figure 3 or descriptions thereof.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g., page 9, line 15). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 1 and 14 are objected to because of the following informalities:

Claims 1 and 14 recite "DSP-2". It is suggested that the first time an abbreviation is used in a claim for a term that is not clearly defined in the specification (pages 1-2), that the abbreviated term be written out in full, followed by its abbreviation in parenthesis. For the purposes of the current examination "DSP-2" was construed as a dual specificity phosphatase.

Claim 6 is objected as dependent from non-elected claim 1. In the interests of the compact prosecution, claim 6 is treated as including all limitations of claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a polynucleotide that encodes at least ten consecutive amino acids of a polypeptide having a sequence corresponding to SEQ ID NO:2. Claim 3 is

drawn to a polynucleotide that encodes at least fifteen consecutive amino acids of a polypeptide having a sequence corresponding to SEQ ID NO:2. These claims are construed as drawn to a polynucleotide of any size and structure that encodes a fragment of at least 10 or at least 15 amino acids of SEQ ID NO:2 that can be flanked by any number of amino acids. The polynucleotides of claim 2 and 3 have no functional limitations. Claims 4 and 5 depend from claims 2 or 3.

Claim 10 is drawn to an antisense polynucleotide comprising at least 15 consecutive nucleotides complementary to a polynucleotide encoding DSP-2 having at least 50% homology to SEQ ID NO:2. Claim 11 is drawn to a polynucleotide that hybridizes to SEQ ID NO:1 under conditions that include a wash in 0.1X SSC and 0.1% SDS at 60° C for 15 minutes. The polynucleotides of claims 10 and 11 have no functional limitations. Claims 12 and 13 depend from claim 10 or 11.

The genus of nucleic acids that comprise these above polynucleotides is a large variable genus with the potentiality of encoding proteins having many different functions. Therefore, nucleic acids encoding many structurally and functionally unrelated proteins are encompassed within the scope of the claims, including partial sequences. The specification discloses only a single species of the claimed genus, a human nucleic acid of SEQ ID NO:1 encoding a DSP-2 polypeptide of SEQ ID NO:2. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties and fails to provide any structure: function

correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 2-6 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding SEQ ID NO:2, does not reasonably provide enablement for a polynucleotide encoding an amino acid sequence at least 50% homologous to SEQ ID NO:2 and retaining DSP-2 function, polynucleotide comprising 15 nucleotides of a complementary sequence and encoding a DSP-2 or unknown activity, polynucleotides encoding polypeptides comprising a fragment of SEQ ID NO:2 of at least 10 or 15 amino acids and encoding a DSP-2 or unknown activity and polynucleotides that hybridize to SEQ ID NO:1 encoding a DSP-2 or unknown activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 6, with dependent claims 8, 9 and 14, is drawn to or dependent from a polynucleotide encoding an amino acid sequence at least 50% homologous to SEQ ID NO:2 and retaining a DSP-2 activity. Claims 2-5 and 10-13 encompass polynucleotides encoding a DSP-2 and polypeptides with unknown activity.

The specification does not support the broad scope of the claims which encompass polynucleotides encoding a DSP-2 polypeptide at least 50% homologous to SEQ ID NO:2 because the specification does **not** establish: (a) regions of the protein structure which may be modified without effecting the DSP-2 activity of the polypeptide of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The specification teaches a polynucleotide of SEQ ID NO:1 encoding a DSP-2 of 188 amino acids (SEQ ID NO:2). The active site domain of said DSP-2 is located at

residues 86-101 of SEQ ID NO:2 (SEQ ID NO:3). However, a fragment of 16 residues is unlikely to exhibit DSP-2 activity and it constitutes less than 10% of the structure. Despite knowledge in the art to produce mutations in proteins, the specification fails to provide guidance as to where, and what type of (i.e., what amino acid to substitute into, add to or delete from the known sequence), changes in amino acid residues will result in a desired enzymatic activity. The amino acid sequence of a protein determines its structural and functional properties, and predictability of what mutations can be tolerated in a protein's sequence and result in a certain activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's function from mere sequence data are limited.

Furthermore, while recombinant and mutagenesis techniques are known, it is not routine in the art to screen large numbers of mutated proteins or genes where the expectation of obtaining similar activity is unpredictable based on the instant disclosure.

As discussed above, claims 2-5 and 10-13 encompass polynucleotides encoding polypeptides with DSP-2 activity and proteins of unknown function. While the specification teaches how to use a polynucleotide encoding a DSP-2 polypeptide, it provides no guidance as to what is the function of other polynucleotides. Without knowing the function of a polynucleotide one of skill in the art would not have known how to use it.

Therefore, one of ordinary skill in the art would require guidance, beyond that provided in the specification, in order to make a polynucleotide encoding a DSP-2 polypeptide having an amino acid sequence at least 50% homologous to SEQ ID NO:2 and to use a polynucleotide encoding a polypeptide of unknown function in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 3, 6, 10 and 11 are rejected under 35 U.S.C. 102(a)as being anticipated by Strausberg (a).

Strausberg (Database EST, accession AI215158, February 2, 1999) teaches an EST of 495 bp encoding "protein tyrosine phosphatase family" member. Said EST has 99.4% identity with nucleotides 273-767 of SEQ ID NO:1. Said EST comprises

nucleotides encoding the active domain of DSP-2. Furhter, DSP-2 is a member of "protein tyrosine phosphatase family" (specification, page 1, lines 30-31). The EST of Strausberg encodes a polypeptide that is more than 50% homologous to SEQ ID NO:2 that comprises at least 10 or 15 amino acids thereof. It comprises 15 nucleotides complementary to SEQ ID NO:1 and will hybridize therewith.

Claims 2, 3, 6, 10 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (B).

Strausberg (Database EST, accession AA926744, June 17, 1998) teaches an EST of 489 bp encoding "protein tyrosine phosphatase". Said EST has 99.0% identity with nucleotides 352-834 of SEQ ID NO:1. Said EST comprises nucleotides encoding the active domain of DSP-2. Furhter, DSP-2 is a "protein tyrosine phosphatase" (specification, page 1, lines 30-31). The EST of Strausberg encodes a polypeptide that is more than 50% homologous to SEQ ID NO:2, that comprises at least 10 or 15 amino acids thereof. It comprises 15 nucleotides complementary to SEQ ID NO:1 and will hybridize therewith.

Claims 2, 3, 6, 10 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg (C).

Strausberg (Database EST, accession AI283262, January 28, 1999) teaches an EST of 441 bp encoding "protein tyrosine phosphatase". Said EST has 100.0% identity with nucleotides 323-763 of SEQ ID NO:1. Said EST comprises nucleotides encoding the active domain of DSP-2. Furhter, DSP-2 is a "protein tyrosine phosphatase" (specification, page 1, lines 30-31). The EST of Strausberg encodes a polypeptide that is more than 50% homologous to SEQ ID NO:2, that comprises at least 10 or 15 amino acids thereof. It comprises 15 nucleotides complementary to SEQ ID NO:1 and will hybridize therewith.

Claim 6 is rejected under 35 U.S.C. 102(a) as being anticipated by Yuan et al.

Yuan et al. (Database GenBank, accession AF038844, January 6, 1999, form PTO-1449, reference CE) teach a 1471 bp polynucleotide encoding an EST of 441 bp encoding "MKP-1 like protein tyrosine phosphatase" of 198 amino acids. Said phosphatase is 52.1% identical to SEQ ID NO:2. DSP-2 is a "protein tyrosine phosphatase" and has a sequence that is least 50% homologous to SEQ ID NO:2 (specification, page 1, lines 30-31; page 2, lines 25-28).

Claims 6, 8, 9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al.

Lal et al. (US Patent 6,165,767) teach a 1729 bp polynucleotide of SEQ ID NO:6 encoding "protein phosphatase-related molecule", "PPRM-3" of SEQ ID NO:5 (198 amino acids) (column 2). Said phosphatase is 52.1% identical to SEQ ID NO:2. Lal et al. teach a vector and a host cell comprising thereof and a method for producing a polypeptide (claims 1, 2, 8-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, 8, 9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausberg (A, B or C).

The teachings of Strausberg are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include any one of human EST sequences taught by Strausberg (A, B or C) in a vector and express it in a host cell. The expressed polypeptide to be used to produce an antibody, for example. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to use said EST sequence or

fragments thereof, as probes or primers in a method for detecting the full length sequence. This is the art recognized use of an EST.

Claims 8, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al.

The teachings of Yuan et al. are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the polynucleotide taught by Yuan et al. in a vector and express the phosphatase in a host cell. One skilled in the art would have been motivated to produce a phosphatase to produce an antibody and to use in various applications. The physiological importance of phosphatases is recognized in the art.

Allowable Subject Matter

Claim 7 is objected but would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

June 27, 2003